In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 13-562V
January 20, 2015
Not to be Published

ISHWAR GOPICHAND and PENNY GOPICHAND, as Parents and Guardians Ad Litem of C.K.G.,	*	
Petitioners,	*	
v.	*	Hepatitis A vaccine; alleged significant aggravation of seizures; no expert support; ruling on the record
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Peter J. Sarda, Raleigh, NC, for petitioners.
Julia W. McInerny, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION[1]

On August 8, 2013, petitioners filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10–34 (2006), on behalf of their daughter C.K.G., alleging that hepatitis A vaccine administered to C.K.G. on August 19, 2010, exacerbated her preexisting migraines and seizures. Pet. at 2.

[1] Because this decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would constitute a clearly unwarranted invasion of privacy. When such a decision is filed, petitioners have 14 days to identify and move to redact such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the categories listed above, the special master shall redact such material from public access.

The undersigned assumes that by "exacerbate," petitioners are claiming that hepatitis A vaccine significantly aggravated C.K.G.'s preexisting complex migraine headaches and seizures. The Vaccine Act defines "significant aggravation" in § 300aa-33(4):

> The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

On June 2, 2014, respondent filed her Rule 4(c) Report recommending that compensation not be awarded in this case. On June 4, 2014, the undersigned held a telephonic status conference with counsel to discuss respondent's report. The undersigned issued an Order on June 4, 2014, setting a deadline of August 29, 2014, for petitioners to file an expert report in support of their allegations.

On August 13, 2014, petitioners filed a motion for additional time, requesting an additional 60 days or until October 28, 2014, to find an expert to support their allegations. The undersigned granted petitioners' motion on August 13, 2014. On October 22, 2014, petitioners filed a second motion for additional time, requesting an additional 65 days or until January 5, 2015, to find an expert to support their allegations. The undersigned granted petitioners' motion on October 23, 2014. On January 5, 2015, petitioners filed a third motion for additional time, requesting an additional 10 days or until January 15, 2015, to find an expert to support their allegations. The undersigned granted petitioners' motion on January 6, 2014.

On January 15, 2015, petitioners filed a Notice stating that "petitioners are unable to obtain a witness who can reasonably expect to qualify as an expert under the Althen standards." On January 20, 2015, the undersigned held a telephonic status conference with counsel, during which petitioners' counsel orally moved for a ruling on the record.

The undersigned **GRANTS** petitioners' motion for a ruling on the record and **DISMISSES** this case for failure to make a prima facie case of causation and/or significant aggravation.

FACTS

Pre-vaccination Records

C.K.G. was born on January 8, 2001. Her mother's pregnancy was complicated with pregnancy-induced hypertension ("PIH") and gestational diabetes mellitus ("DM"). Med. recs. Ex. 1, at 63.

On February 13, 2002, at Jacksonville Children's Clinic, C.K.G. at 13 months was diagnosed with esotropia (being cross-eyed). Id. at 155.

On August 15, 2002, C.K.G. at 19 months was diagnosed with gross motor delay. Id. at 23.

On August 19, 2002, C.K.G. was evaluated at Onslow Memorial Hospital Department of Rehabilitation, where physical therapist Leslie A. Mosier noted that C.K.G. at 19 months had gross motor delays. Id. at 63. C.K.G.'s neuromuscular tone in her upper and lower extremities was mildly decreased. Id. Her equilibrium was mildly decreased, secondary to poor proximal strength and control. Id. She had bilateral winged scapulas. Id.

On September 9, 2002, PT Mosier recommended that C.K.G. receive a full speech language pathology evaluation. Id. at 89.

On February 13, 2003, C.K.G. was at Jacksonville Children's Clinic, where she was diagnosed with mild developmental delay, strabismus (with a history of ophthalmologic referral at six months), gross motor delay likely secondary to decreased lower extremity tone, and delayed walking. Id. at 24–25. She was referred for a neurology consultation. Id. On the day before this examination, C.K.G. was diagnosed with hypotonia. Id. at 23.

On June 6, 2006, when C.K.G. was five years old, she was at Jacksonville Children's Clinic, complaining that the right side of her head hurt for two hours. Her father, a pediatrician, said she did not have fever. Id. at 15. A Lab Corp. test on June 6, 2006, showed that C.K.G. had elevated tryptase, indicating she experienced a systemic mast cell event. Id. at 6. On the same day, Dr. Dean Batten did a CT scan of C.K.G.'s brain, noting she had a sudden, severe headache in the right-sided/temple region and a fever of 101.8 degrees. Id. at 45. The CT scan was normal. Id. On the same day, C.K.G. was carried from home to Onslow Memorial Hospital ED with a headache and a fever of 101.2 degrees. Id. at 50. She complained of right-sided splitting headache with fever since noon. Id.

From July 27 to 28, 2006, C.K.G. had an ambulatory EEG under the direction of neurologist Dr. Christine T. Burch. Id. at 43–44. The EEG was abnormal due to the presence of a generalized spike in wave and poly spike in wave discharge that was somewhat poorly organized. Dr. Burch noted, "This indicates most likely primary generalized epilepsy . . . ." Id.

On November 10, 2006, C.K.G. saw a pediatric and adult urologist, Dr. Robert T. Bennett, for lysis of her labial lesions. Id. at 40.

On April 17, 2007, C.K.G. visited Jacksonville Children's Clinic, complaining of a temporal headache. Id. at 4.

On April 23, 2007, C.K.G. had surgery for a fracture of her left arm due to falling off a balance beam during gymnastics. Id. at 213.

On December 3, 2008, C.K.G. visited Jacksonville Children's Clinic, complaining of numbness in her hands and right jaw, right-sided headache, and transient weakness that lasted about five minutes. Id. at 99. She was diagnosed with a probable seizure. Id.

On December 4, 2008, C.K.G. visited East Carolina Neurology, recounting her symptoms of right jaw pain, left hand weakness, and left distal lower extremity weakness leading to dragging. Id. at 263. This lasted 15 minutes, and she had a headache afterwards. Id. The neurologist's differential diagnosis was seizure, classic migraine, or transient ischemic attack ("TIA"). Id.

On March 20, 2009, C.K.G. saw Dr. Burch, her neurologist, complaining of weakness on one side lasting 15 minutes, followed by a headache, which Dr. Burch thought most likely a classic migraine. Id. at 97. Dr. Burch noted that C.K.G.'s methylenetetrahydrofolate reductase ("MTHFR") level was slightly abnormal, for which C.K.G. took folate. Id. Dr. Burch's diagnosis was classic migraine involving a neurologic deficit of hemiplegia for 15 minutes. Id.

Post-vaccination Records

On August 19, 2010, C.K.G. received hepatitis A vaccine. Med. recs. Ex. 2, at 1.

On August 20, 2010, C.K.G. visited Pitt County Memorial Hospital. Med. recs. Ex. 5, at 1. A respiratory culture showed moderate gram positive cocci. Id. at 5. A brain MRI done on the same day was normal. Id. at 6. A chest x-ray done the same day showed streaky opacities in the right upper lung zone, which might represent atelectasis or possibly developing infiltrate. Id. at 7. Aspiration was a consideration. Id. Dr. Douglas R. Gallo took a history and physical on August 20, 2010. Id. at 8–10. After C.K.G.'s vaccination, she ate at Chick Fil A and went home. Id. at 8. She helped pack a van for her father's trip and ate lasagna at 7:00 p.m. Id. C.K.G.'s mother suspected C.K.G. fell behind on her fluids. Id. C.K.G. had not had any of the G2 Gatorade she normally drank. Id. At 11:15 p.m., while the family was driving, C.K.G. was in the back seat when she started gurgling and slumped over. Id. Her eyes deviated to the right, and she drooled. Id. She was not speaking or following commands. Id. There was some vomitus. Id. She had tonic movements, but no loss of bowel or bladder. Id. This lasted five minutes. Id. EMS took her to Duplin General ED, where she had a second seizure. Id. This time, she was incontinent of urine. Id. Her seizures lasted for over 32 minutes. Id. Her left arm where she received the hepatitis A injection was sore. Id. Family history shows that C.K.G.'s sister has positional orthostatic tachycardia syndrome ("POTS"), and her brother has an atrial flutter. Id. at 9. C.K.G.'s temperature was 99 degrees. Id. Her white blood count was elevated at 16.4. Id. She had a history of seizing when she was dehydrated. Id. at 10.

On August 20, 2010, Dr. Burch, C.K.G.'s neurologist, wrote that C.K.G. had a history of seizures at age five, possibly secondary to morphine. Id. at 19. She had an episode of status epilepticus lasting 30 minutes. Id. She had a history of complicated migraines and had a mild delay with speech articulation. Id. C.K.G. had abnormal EEGs in the past with slowing of the

left hemisphere. Id. She had a history of strabismus (when the eyes do not line up in the same direction). Id. She had a history of complicated migraine vs. partial seizure two years earlier in 2008. Id. at 20. She had delay and hypotonia. Id. Her temperature was 99.5 degrees, but over 72 hours, she had a maximum temperature of 102.2 degrees and a minimum of 99 degrees, with an average temperature of 100.2 degrees. Id.

On August 20, 2010, Dr. Gallo noted that C.K.G.'s mucus plug was suctioned. Id. at 33.

An MRI of C.K.G.'s brain on August 20, 2010 was normal. Id. at 34. Dr. Gallo stated the next day that infection seemed unlikely given C.K.G.'s clinical status. Id. at 37. However, given the risk of fever and aspiration during her seizure and postictal periods, C.K.G. would be administered a second dose of Ceftriazone that day. Id. at 37. When C.K.G. was sent home, she was prescribed Augmentin for five days in order to complete a seven-day course of antibiotics. Id.

On August 21, 2010, Dr. Lilan Dusabe-Ziherambere, a pediatrician, noted that C.K.G. was extubated at 12:15 p.m. on August 20, 2010. Id. at 13. Just prior to her extubation, C.K.G. had fever and thick secretions. Id. Therefore, trachial aspirate and blood cultures were obtained, and C.K.G. was started on an antibiotic, Rocephin. Id. C.K.G.'s trachial aspirate grew out oropharyngeal flora. Id. at 18.

On August 22, 2010, C.K.G. was discharged from the hospital with a diagnosis of status epilepticus and fever from an unclear source. Id. at 17. She was prescribed Keppra, Diastat for seizures, and folic acid due to her MTHFR. Id.

On September 15, 2012, two years later, C.K.G. was brought to Vidant Medical Center with altered mental status, right-sided weakness, slurred speech, and confusion. Id. at 173. Her mother reported this began like previous events at 2:00 p.m. Id. C.K.G. presented at Onslow ED with her right hand clenched and painful. Id. She had lethargy and malaise. Id. at 173–74. Her temperature was 97.3 degrees. Id. at 174. Dr. Inga S. Aikman saw her that day and said C.K.G. was taking Topomax and Trileptal. Id. at 176. C.K.G.'s seizures began on September 14, 2012, when she complained of seeing a white light and then developed pain and clenching of her right hand. Id. Later that night, she was found confused and unable to talk or walk. Id. Her parents reported that she had similar episodes within the past year, marked by pain in her right hand, which traveled to the right side of her face. Id. She had these episodes every six months. Id. The most recent spell was at the beginning of the month. Id. She had several brain MRIs, which were normal. Id. She had a history of gross motor delay and did not walk until she was 16 months of age. Id. The differential diagnosis was that she was most likely having a complex migraine, but Dr. Aikman noted pseudoseizure[2] should also be considered. Id. at 179.

[2] Pseudoseizure is "an attack resembling an epileptic seizure but being a type of conversion disorder; it lacks the electroencephalographic characteristics of epilepsy and the patient may be able to stop it by an act of will." Dorland's Illustrated Medical Dictionary 1546 (32d ed. 2012). Conversion disorder is "a

On September 15, 2012, C.K.G. saw Dr. Burch, her neurologist, who noted a one-day history of headache, fever, altered mental status, and questionable weakness on her right side. Id. at 188. The weakness was questionable because, on examination, C.K.G. had no weakness, sensory deficits, or cranial nerve deficits. Id. C.K.G. spoke in one-word answers and called Dr. Burch "C.K.G." Id. That week C.K.G. struggled with her accelerated math program with tutoring and had difficulty sleeping because of it. Id. "It should be noted her sister years ago was admitted for pseudoseizures after being in an accelerated math program." Id. The differential diagnosis was seizure, complicated/confusional migraine, encephalitis, or functional cause (no physiologic basis). Id. Family history showed C.K.G.'s brother had hypotonia, and her sister had pseudoseizures. Id. at 189.

Dr. Burch performed an EEG on C.K.G. on September 15, 2012, which was abnormal. Id. at 203. C.K.G. had asymmetric background with slowing of the left hemisphere. Id.

For the sake of brevity, the undersigned omits a number of additional records and summarizes a recent record from Duke Medicine, dated July 15, 2013. Med. recs. Ex. 4, at 6–7. Nurse Practitioner Lyndsey Nicole Prange noted C.K.G.'s history of probable hemiplegic migraines with recurrent headaches. Id. She had three episodes of right hemiplegia in 2008, 2011, and recently. Id. The last episode required hospitalization at Duke on March 28, 2012, and was accompanied by aphasia. Id. C.K.G. had a history of generalized tonic-clonic status epilepticus, the first episode occurring in June 2006, the second episode in "September[3]" 2010 after an immunization, and the third episode (a complex partial seizure) occurring on March 30, 2013, including loss of consciousness, left nystagmus, and foaming at the mouth. Id. C.K.G.'s MTHFR mutation required use of folic acid. Id. She had an abnormal anticardiolipin antibody and von Willibrand titers. Id. C.K.G. had vitamin D deficiency and mitochondrial DNA whole gene sequencing, 2 VUS (variant of unknown significance). Id.

DISCUSSION

The first issue in this case is whether C.K.G.'s condition after her vaccination was substantially worse than her condition before vaccination. Before vaccination, C.K.G. had gross motor delay, speech dysfunction, complicated migraine headaches, seizures, and abnormal

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mental disorder characterized by conversion symptoms (loss or alteration of voluntary motor or sensory functioning suggesting physical illness, such as seizures, paralysis, dyskinesia, anesthesia, blindness, or aphonia) having no demonstrable physiological basis and whose psychological basis is suggested by (1) exacerbation of symptoms at times of psychological stress, (2) relief from tension or inner conflicts (primary gain) provided by the symptoms, or (3) secondary gains (support, attention, avoidance of unpleasant responsibilities) provided by the symptoms." Id. at 549. "Symptoms are neither intentionally produced nor feigned. . . ." Id.

[3] This should be August 2010.

EEGs. After vaccination, C.K.G. had seizures and migraine headaches. The second issue, assuming there was substantial deterioration, is whether the vaccine was the causal factor.

To satisfy their burden of proving causation in fact, petitioners must prove by preponderant evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Sec'y of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" i.e., "evidence in the form of scientific studies or expert medical testimony[.]"

418 F.3d at 1278.

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Id. at 1148.

Petitioners must show not only that but for hepatitis A vaccination, C.K.G. would not have had a seizure and migraines, but also that the vaccine was a substantial factor in causing her seizure and migraines. Shyface v. Sec'y of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Although petitioners allege that hepatitis A vaccination exacerbated C.K.G.'s seizure disorder and migraines, the medical records do not prove she had worsening of her seizure disorder or migraines. Petitioners did not file a medical expert report in support of their allegations. The undersigned gave petitioners 225 days, over seven months, to find an expert. They did not find one. The Vaccine Act does not permit the undersigned to rule for petitioners based on their claims alone, "unsubstantiated by medical records or by medical opinion." 42 U.S.C. § 300aa-13(a)(1).

Thus, petitioners have not made a prima facie case of causation.

The undersigned **GRANTS** petitioners' motion for a ruling on the record and **DISMISSES** this case for petitioners' failure to prove the allegations in their petition by a preponderance of the evidence. 42 U.S.C. § 300aa-13(a)(1)(A).

CONCLUSION

This petition is **DISMISSED**. In the absence of a motion for review filed pursuant to RCFC, Appendix B, the clerk of the court is directed to enter judgment herewith.[4]

IT IS SO ORDERED.

January 20, 2015
DATE

s/Laura D. Millman
Laura D. Millman
Special Master

[4] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party, either separately or jointly, filing a notice renouncing the right to seek review.